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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,495	09/15/2003	Yoshiyuki Shoji	H6807.0001/P001-A	7412

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/661,495

**Applicant(s)**

SHOJI ET AL.

**Examiner**

Patrick T. Lewis

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-31 is/are pending in the application.
- 4a) Of the above claim(s) 12-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/808,157.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01132004, 09152003
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. The current status of the parent nonprovisional application(s) should be included/updated. Application 09/808,157 has been allowed and is now US Patent 6,692,703.

### ***Election/Restrictions***

2. Applicant's election without traverse of Group I (claims 1-5 and 28-31) in the reply filed on July 22, 2004 is acknowledged.

3. Claims 12-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 22, 2004.

### ***Response to Amendment***

4. In the Response dated July 22, 2004, claims 1-5 were canceled. Claims 12-31 are pending. Claims 12-27 are drawn to a nonelected invention. An action on the merits of claims 28-31 is contained herein.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsythe, Jr. et al. US 4,214,993 (Forsythe) in combination with Sauer et al. EP 0 969 090 A1 (Sauer).

Claims 28-31 are drawn to a nucleic acid purification method using a tip incorporating a solid phase containing a nucleic acid capturing agent, comprising the steps of: contacting a nucleic acid containing solution with a solid phase; discharging the nucleic acid containing solution outside the tip; contacting a washing solution with

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the solid phase; discharging the washing solution outside the tip; and discharging air into the tip after discharging washing solution so that remaining liquid is discharged. Claim 29 recites an additional washing step. Claim 30 further comprises contacting an eluent with the solid phase after discharging the remaining liquid and discharging the eluent outside the tip. Claim 31 further comprises blocking outflow of the solid phase by a blocking member provided on the tip.

Forsythe teaches an apparatus (nested spin column) and method for separating fluids (Figures 1-3; column 2, line 18 to column 4, line 66). An extraction cartridge **32** containing a separating column with a resin bed is separated from the nested stack and placed in a centrifuge rotor, in an orientation so that fluids are moved through the column by centrifugal force. The extraction cartridge is positioned radially inside of a circumferentially positioned first container or cup **32** and a second container or cup **36**. The bottom tip end of the extraction cartridge **16** is in the form of a nozzle **28** which is tapered to a general point. Spherical porous support **30**, made of a typical inert plastic, are placed at the top and bottom of the particular separating material **26** formed in the column to maintain the particles in place. Various materials may be used for the separating column. The centrifuge rotor has a capability of switching the fluid flow path from the exit of the separating column in the extraction cartridge such that the effluent from the extraction cartridge such that the eluent from the extraction cartridge may be passed by choice either to the first cup **32** or to the second cup **36**. The rotor used is a swinging bucket rotor capable of holding a plurality of sets of extraction cartridges, first cup, and second cups. The centrifugal force acting on the horizontal column forces the

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sample through the resin bed at a controlled flow rate. The materials to be extracted from the sample are retained by the resin while other materials pass through the column and are collected by the first cup. Next, wash solvent or reagent is delivered to the fluid distribution hub of the rotor. The wash is divided into equal aliquots and directed to the resin beds in each separating column and collected in each first cup. In this step the wash removes unadsorbed sample components from the resin bed. Centrifugal force passes residual wash to the first cup. Eluting solvent is dispensed from a solvent reservoir and aliquoted to the several cartridge positions. The solvent passes through the column of the extraction cartridge under the influence of centrifugal force, extracting the adsorbed materials which are eluted from the resin bed of the column and collected in the second cup. If desired, a pump (suction or pressure) may be used to move the fluid through the column. Compressed gas may be used as the driving force.

Forsythe differs from the instant invention in that Forsythe differs from the instant invention in that: 1) Forsythe does not explicitly teach the purification of nucleic acids and 2) Forsythe does not explicitly teach additional washing steps; however, the deficiencies of Forsythe would have been obvious in view of Sauer.

Sauer teaches a method for isolating plasmid DNA from bacterial overnight cultures (column 10, lines 1-44). The method comprises: a) applying the sample to the spin column; b) centrifuging for 1 minute and discarding the flow-through; c) washing the column, centrifuging for 1 minute, and discarding the flow-through; d) washing the column, centrifuging for 2 minute, and discarding the flow-through; and e) eluting the DNA.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to purify a nucleic acid containing solution using the nested spin column taught by Forsythe. Spin columns are routinely used to purify nucleic acids as demonstrated by Sauer. The selection of a suitable conventional purification technique is well within the purview of one of ordinary skill in the art. It would have also been obvious to one of ordinary skill in the art at the time of the invention to perform multiple washings as taught by the prior art. One would have been motivated to do so in order to achieve greater purity of the product.

### ***Conclusion***

9. Claims 12-31 are pending. Claims 12-27 are drawn to a nonelected invention. Claims 28-31 are rejected. No claims are allowed.

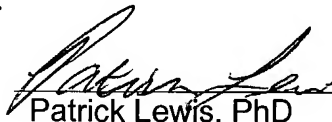
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### **Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday between 10 am - 2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patrick Lewis, PhD  
Examiner  
Art Unit 1623

ptl